

***In the Claims:***

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently amended): A method for evaluating the efficacy of a therapeutic agent in the body of a mammal, wherein said agent acts to stimulate apoptosis, ~~which comprises said method comprising:~~

~~obtaining a first sample of whole blood, plasma or serum, from a mammal to be treated with said therapeutic agent a sample of a body tissue in which tumor cells are present or a body fluid, wherein said first sample said tissue or fluid can contain a 17 kDa fragment of caspase 3, said fragment produced by specific cleavage of caspase 3 *in vivo*, wherein said first sample has been obtained from said mammal before administration of said therapeutic agent to said mammal;~~

purifying said first sample using column chromatography;  
assaying said first sample to determine the amount of said cleaved 17 kDa fragment of caspase 3 present;

administering said therapeutic agent to said mammal;  
obtaining a second sample ~~of whole blood, plasma or serum, said body tissue or said body fluid~~ from said mammal;

purifying said second sample using column chromatography; and  
assaying said second sample to determine the amount of said 17kDa fragment of cleaved caspase 3 present;

wherein an increase in the amount of said 17 kDa fragment measured in said second sample over the amount measured in said first sample indicates correlates with apoptosis stimulation and efficacy of said therapeutic agent.

2-4. (Cancelled).

5. (Original): The method of claim 1, wherein said therapeutic agent comprises a chemotherapeutic agent, a radiotherapeutic agent, a tumor suppressing nucleic acid, an oligonucleotide or a combination thereof.

6. (Original): The method of claim 1, wherein said therapeutic agent comprises a nucleic acid.

7. (Original ): The method of claim 6, wherein said nucleic acid comprises a DNA molecule which encodes a wild type p53 molecule, an RB molecule, an RB94 molecule, an apoptin molecule or an antisense HER-2.

8. (Original): The method of claim 1, wherein said therapeutic agent is administered as a complex with a ligand-cationic liposome.

9. (Original): The method of claim 8, wherein said ligand comprises transferrin, folate or an anti-transferrin receptor single chain antibody fragment.

10. (Original): The method of claim 8, wherein said ligand comprises an antibody or antibody fragment.

11. (Original): The method of claim 10, wherein said antibody or antibody fragment binds to the transferrin receptor or to HER-2.

12. (Original): The method of claim 10, wherein said antibody fragment is an scFv fragment.

13. (Original): The method of claim 8, wherein said liposome comprises a mixture of dioleoyltrimethylammonium phosphate (DOTAP) and dioleoylphosphatidylethanolamine (DOPE) or cholesterol or a combination thereof or a mixture of dimethyldioctadecylammonium bromide (DDAB) and DOPE or cholesterol or a combination thereof.

14. (Currently Amended): The method of claim 8, wherein said therapeutic agent is further comprises a chemotherapeutic agent or a radiotherapeutic agent.

15. (Currently Amended): The method of claim 1, wherein the amount of said cleaved 17 kDa subunit in said second sample is at least 1.5 to about 2 times greater than the amount of said cleaved subunit in said first sample.

16. (Currently Amended): A method for evaluating the efficacy of a therapeutic agent in the body of a mammal, wherein said agent acts to stimulate apoptosis, which comprises:

obtaining a first sample of whole blood, plasma or serum ~~blood or a blood component~~ from a mammal to be treated with said therapeutic agent;

purifying said first sample using column chromatography;

assaying said first sample to determine the amount of a 17 kDa fragment of caspase 3 present in said first sample, said fragment produced by specific cleavage of caspase 3 in vivo;

administering said therapeutic agent to said mammal;

obtaining a second sample of whole blood, plasma or serum ~~blood or a blood component~~ from said mammal;

purifying said second sample using column chromatography; and  
assaying said second sample to determine the amount of said 17kDa fragment of  
cleaved caspase 3 present in said sample;  
wherein an increase in the amount of said 17 kDa fragment measured in said second  
sample over the amount measured in said first sample indicates correlates with apoptosis  
stimulation and efficacy of said therapeutic agent.

17. (Cancelled).
18. (Original): The method of claim 16, wherein said therapeutic agent comprises a chemotherapeutic agent, a radiotherapeutic agent, a tumor suppressing nucleic acid, an oligonucleotide or a combination thereof.
19. (New): The method of claim 1, wherein said column chromatography comprises P6 or P30 column chromatography
20. (New): The method of claim 1, wherein said mammal is tumor-bearing.
21. (New): The method of claim 16, wherein said column chromatography comprises P6 or P30 column chromatography
22. (New): The method of claim 16, wherein said mammal is tumor-bearing.